

Tab A-1

State Settlement Agreement

Part I: Parties

This Settlement Agreement (hereinafter the "Agreement") is entered into by and between the STATE OF MONTANA (hereinafter the "STATE") and BAYER Corporation (hereinafter "BAYER") (hereinafter collectively referred to as the "Parties") through their authorized representatives.

Part II: Preamble

As a preamble to this Agreement, the Parties agree to the following:

- A. BAYER Corporation is a corporation organized under the laws of Indiana. Its headquarters are in Pittsburgh, Pennsylvania. BAYER is a manufacturer of pharmaceutical and biological products. Miles, Inc. and Cutter Laboratories, Inc. (which along with BAYER Corporation, shall be referred to hereafter as "BAYER"), were predecessor organizations that ultimately were merged into the company that became known as BAYER Corporation. At all relevant times, BAYER manufactured, marketed and sold certain drugs and biological products to -- among others -- (1) healthcare providers, (2) "full-line" drug wholesalers, and (3) specialized drug wholesalers sometimes called "distributors."
- B. The STATE contends that BAYER caused to be submitted claims for payment to the STATE's Medicaid Program, established by Title XIX of the Social Security Act.
- C. The STATE contends that it has civil claims against BAYER under various state statutes and common law for engaging in the following conduct during the period January 1993 through August 1999 involving the marketing and sale of Koate-HP

Antihemophilic Factor (Human), Kogenate Antihemophilic Factor (Recombinant), Konyne-80 Factor IX Complex (Human), Gammimune N, 5% Immune Globulin Intravenous (Human, 5%), Gammimune N, 10% Immune Globulin Intravenous (Human, 10%), and Thrombate III Antithrombin III (Human) (collectively referred to hereafter as the Qui Tam Drugs):

- i) The STATE contends that BAYER, in a manner similar to the practices of certain other manufacturers, knowingly and intentionally engaged in a marketing scheme whereby it set the Average Wholesale Prices ("AWPs") of the Qui Tam Drugs at levels far higher than what the vast majority of its customers actually paid for these products when purchasing either directly from BAYER or through a wholesaler. Because the majority of Medicaid programs use AWP as a benchmark in determining reimbursement rates, the STATE contends that as a result of BAYER's actions, BAYER's customers received reimbursement from state Medicaid programs at levels far higher than their actual costs.
- ii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that reimburse on the basis of Wholesale Acquisition Cost ("WAC") by, among other actions, representing to third party reporting services such as First DataBank and Medi-Span that it did not sell the Qui Tam Drugs through wholesalers and by misleading Medicaid officials about the prices it charged to wholesale purchasers in order to avoid reporting accurate

wholesale or distributor price information that would have affected the reimbursement levels of the Qui Tam Drugs in states that use WAC as the reimbursement benchmark. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.

- iii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that rely on actual acquisition cost information about the prices at which BAYER sold the Qui Tam Drugs to its customers, including home health agencies. The STATE alleges that BAYER did so by falsely reporting its prices on surveys and by providing invoices to home health companies that did not reflect the actual net cost of the Qui Tam Drugs to customers. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.
- iv) The STATE contends that BAYER knowingly and intentionally misreported and underpaid its Medicaid Rebates for the Qui Tam drugs, *i.e.*, the amounts that it owed to the Medicaid program under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. BAYER generally was required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price and "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The STATE alleges that BAYER misreported and

underpaid its Medicaid rebates to all states by calculating its Best Prices for the Qui Tam Drugs without factoring in the value of discounts, rebates, short-dated goods discounts, unrestricted educational grants, free goods, chargebacks, and other price reductions which were not disclosed to the states or the federal government or the Medicaid programs.

BAYER's conduct and transactions referenced herein Paragraph II(C)(i-iv) are hereinafter referred to as the "Covered Conduct."

- D. The STATE contends that it has certain administrative claims against BAYER for administrative and monetary penalties under state and federal law for the Covered Conduct.
- E. BAYER denies the STATE's contentions as set forth in Paragraphs II (B – D) and denies that it has any liability relating to these allegations.
- F. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of mutual desire to settle their disputes, the Parties reach a full and final settlement as set forth below.
- G. This Agreement does not constitute an admission by BAYER or evidence of any liability or wrongful conduct.
- H. Concurrent with this Agreement, BAYER is entering into a settlement agreement regarding the Covered Conduct with the United States of America and with the relator (the "Relator") in a lawsuit filed pursuant to the qui tam provisions of the federal False Claims Act, Civil Action No. 95-95-1354 (S.D. Fla., under seal), and BAYER also is entering into a Corporate Integrity Agreement with the Office of

Inspector General of the United States Department of Health and Human Services and into similar settlement agreements with numerous other states.

Part III: Terms and Conditions

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. (a) BAYER agrees to pay the United States, the individual states and the Relator the maximum collective sum of fourteen million dollars (\$14,000,000) (the "Settlement Amount"). BAYER agrees to make payment of the federal share of the Settlement Amount and the Relator's share of the Settlement Amount pursuant to the terms of BAYER's separate settlement agreement with the United States and the Relator. BAYER agrees to pay the maximum sum of six million, one hundred seventy-two thousand dollars (\$6,172,000) of this total (the "Total State Settlement Amount"), representing the state-funded portions of the claims settled for the participating states' Medicaid programs, to the participating states identified on Exhibit "A" to this Agreement. The STATE's share of the Total State Settlement Amount is \$6,599.26 (the "Individual State Settlement Amount").

(b) Within three business days of the Effective Date of the federal settlement agreement, the Effective Date of the Corporate Integrity Agreement or the execution of an escrow agreement with the State of New York, whichever is later, BAYER shall deposit the Total State Settlement Amount in an interest bearing escrow account under the custody and control of the State of New

York Medicaid Fraud Control Unit, which shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in c).

- (c) The STATE shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after receipt by the Escrow Agent of a copy of this Agreement executed by both the STATE and BAYER, provided, however, that the STATE shall not be entitled to disbursement of the Individual State Settlement Amount until the Escrow Agent has received fully executed state settlement agreements from all those states identified on Exhibit "B" (the "Threshold States") . Any escrowed funds not disbursed within 200 days after the Escrow Agent has received the Total State Settlement Amount shall be disbursed to BAYER.
- 2) Subject to the exceptions in Paragraph III(6) below, in consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE (on behalf of itself, its officers, agents, agencies and departments) agrees to release BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders from any civil or administrative monetary claim, action, suit or proceeding the STATE has or may have under any source of law for the Covered Conduct. The payment of this settlement amount fully discharges BAYER from any obligation to pay restitution, damages, and or any fine or penalty to the STATE for the Covered Conduct.

- 3) In consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicaid program against BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders for the Covered Conduct as relates to the STATE's Medicaid program, except as reserved in Paragraph III(6), below, and as reserved in this Paragraph.
- 4) In the event that any person(s) has(have) filed any qui tam "whistleblower" actions under the laws of the STATE relating to the Covered Conduct, it is the STATE's understanding that: such person(s) shall take such actions as are necessary and appropriate to dismiss said actions against BAYER and secure state court approvals, to the extent necessary, of this Agreement; and, the STATE agrees that it shall negotiate in good faith with the person(s) as to the person's(s') share in connection with the state action. In the event that an agreement cannot be reached, the STATE agrees that it shall submit that issue to the state court having jurisdiction. The STATE shall also join in any necessary motions before the state court to secure approvals of this Agreement.
- 5) BAYER fully and finally releases the STATE, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which BAYER has asserted, could have asserted, or may assert in the future against the STATE, its agencies, employees, servants, and agents,

related to the Covered Conduct and the STATE's investigation and prosecution thereof.

- 6) Notwithstanding any other terms of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including BAYER) are any and all of the following:
 - (a) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code) or the STATE's Revenue Code;
 - (b) Any criminal liability;
 - (c) Except as explicitly stated elsewhere in this Agreement, any administrative liability, including mandatory exclusion from any state health care programs;
 - (d) Any civil or administrative liability that BAYER has or may have under any state statute, regulation or rule not released in Paragraph III(2) above;
 - (e) Any claims based upon such obligations as are created by this Agreement;
 - (f) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by BAYER,
 - (g) Any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
 - (h) Any claims based on a failure to deliver items or services due; and,
 - (i) Any civil or administrative claims against individuals, including current or former directors, officers, employees, agents or shareholders of defendant BAYER, who are criminally convicted in relation to the Covered Conduct.

- 7) BAYER has entered into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services (“OIG”), the goal of which is to ensure the accurate and complete communication of drug pricing information to specified drug price reporting services and the states. BAYER acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the STATE and that the Corporate Integrity Agreement does not preclude the STATE from taking any appropriate action against BAYER for future conduct under the STATE's laws.
- 8) BAYER shall report certain drug and biological product pricing information to the STATE's Medicaid Program as set forth herein for the purpose of furnishing the STATE with true pricing information that accurately reflects the prices at which actual purchasers buy the drug and biological products sold by BAYER. BAYER understands that this information may be relied upon by the STATE in establishing reimbursement rates for drugs and biological products.
 - a) Price Reporting: Thirty days after the last day of each calendar quarter, BAYER shall report, in accordance with sub-paragraph (b), the average sale price of each of its drugs and biological products identified by BAYER'S NDC codes that are or shall be reimbursed by the STATE's Medicaid Program, to First DataBank and to the STATE's Medicaid Program, except that the first such report shall be submitted on February 28, 2001, or fifteen days after the Effective Date of this Agreement, whichever is later. If appropriate to reflect changes in the sources from which the STATE's Medicaid program

receives its pricing information, BAYER agrees that, upon the receipt of a written request from the STATE, it will report the prices to a drug pricing reporting source other than, and in addition to, First DataBank, subject to reasonable provisions equivalent to those in place with First DataBank to ensure the confidentiality of that information.

- b) Average Sale Price Reporting Procedure: The price reported by BAYER with respect to each dosage form, strength and volume of the drug or biological product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package), shall be the average of all final sale prices charged by BAYER for the drug or biological product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals. The prices identified in the calculation of the average sale price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates* and all other price concessions provided by BAYER to any relevant purchaser, as earlier defined in this paragraph, that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the average sale price shall not include the value of bona fide charity care or grants. The average sale price reported shall be properly weighted to reflect

the volume of sales at each sale price, *i.e.*, for each NDC code, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by BAYER, net of all price reductions as defined above, for a drug or biological product in a quarter by the total number of units of that drug or biological product sold in that quarter. The methodology by which BAYER has calculated average sale prices in accordance with these standards shall be identified to the STATE as provided in Paragraph III.8(d).

- c) Limitations on Reporting of Average Wholesale Price: With respect to the Qui Tam Drugs, BAYER shall not report an AWP to First DataBank, or any other reporting service, to be used for purposes of setting Medicaid reimbursement prices for the Qui Tam Drugs, and BAYER shall expressly inform such reporting services to this effect. This restriction shall not limit BAYER's ability to report AWP information for the Qui Tam Drugs to price reporting services for uses unrelated to Medicaid, or its ability to report AWP information for any purposes for drugs or biological products other than the Qui Tam drugs.
- d) Certification Requirement: With each report of average sale price information BAYER sends to the STATE Medicaid Agency, BAYER shall also provide a detailed description of the methodology used to calculate the average sale price. A high managerial agent of BAYER

* The term "rebate" as used here is not understood to include any payments made by BAYER to the States pursuant to the Medicaid Rebate Program.

will certify that the average sale prices reported therein are the prices that have been reported to First DataBank, or any successor reporting agency, and that they have been calculated in accordance with the described methodology. Said certification shall be in the form annexed to this Agreement and shall include an acknowledgment that the average sale prices reported will be filed with and used in the administration of the STATE's Medicaid program. To the extent that BAYER's methodology involves accruing for the impact of future events, BAYER shall include a description of its accrual methodology in its certification, and shall on a quarterly basis evaluate such methodology in light of its actual experience and make any appropriate adjustments.

- e) It is understood that BAYER considers the average sale price information and the methodology by which it is calculated to be confidential commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of BAYER. It is further understood, however, that all information provided by BAYER to the STATE Medicaid Program pursuant to this Agreement shall be made available to the STATE's MFCU upon request.
- f) BAYER agrees to submit average sale price information in accordance with this paragraph for a period of five years from the Effective Date of this Agreement.

- g) BAYER shall retain all workpapers and supporting documentation relating to the average sale prices of its drugs for six years after the date of each certification and will make such documentation available for inspection by the STATE's Medicaid Program and the STATE's MFCU.
- 9) BAYER waives and will not assert any defenses BAYER may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution or any corresponding section of the STATE's Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the United States Constitution or the corresponding section of the STATE's Constitution, this settlement bars a remedy sought in such criminal prosecution or in any administrative action that has not been released pursuant to this Agreement.
- 10) BAYER covenants to cooperate fully and truthfully with the STATE in any ongoing investigation or investigation commenced within five years of the Effective Date of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom BAYER has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct. More specifically, upon reasonable request from the STATE:
 - (a) BAYER will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and

employees for interviews and testimony relating to the Covered Conduct, consistent with the rights and privileges of such individuals. To encourage the cooperation of such individuals, BAYER agrees to advise such individuals in writing that the STATE wishes to interview them or seek their testimony, and that the individuals' cooperation is in the best interest of BAYER. Cooperation provided pursuant to this subparagraph will include identification of witnesses who, to BAYER's knowledge, may have material information related to the STATE's inquiry. The testimony referred to in this paragraph includes, but is not limited to, testimony deemed necessary by the STATE or a court to identify or establish the source, original location, authenticity, or other evidentiary foundation for any documents and to authenticate such documents in any criminal, civil and administrative investigations and proceedings in which the STATE is involved.

- (b) BAYER will provide copies of non-privileged documents and records in its possession, custody or control relating to the Covered Conduct and relating to the subject of the STATE's inquiry. In connection with this, BAYER shall provide such technical assistance as is necessary to facilitate the STATE's access to any computerized information covered by this Paragraph.
- (c) Nothing in this agreement shall be construed as a waiver by BAYER of its attorney-client privilege or work product privilege. Notwithstanding that

fact, the existence of any such privilege does not affect BAYER'S obligation to comply with this Agreement.

- 11) This Agreement is intended to be for the benefit of the Parties only and, except as stated herein, the Parties do not by this instrument release any claims against any other person or entity, including any individual or entity that purchased drugs or biological products from BAYER.
- 12) The STATE acknowledges BAYER's cooperation in the STATE's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties upon the request of BAYER. The making of this Agreement, and BAYER's provision of information pursuant to it, shall not be construed by the STATE as a basis for the exclusion of any of BAYER's products from the STATE's formulary.
- 13) Concurrent with the execution of this Agreement and payment of the Settlement Amount, the STATE agrees to dismiss with prejudice any lawsuit against BAYER, including any STATE qui tam "whistleblower" lawsuit currently pending against BAYER in the courts of the STATE, relating to the Covered Conduct.
- 14) Nothing in this Agreement shall be construed to abrogate or alter any existing obligation of BAYER pursuant to State law.
- 15) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.
- 16) Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

- 17) This agreement is governed by the laws of the State of Montana.
- 18) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

STATE:

[For the submission of average sale price data]

**Pharmacy Director
42 Olive Street
Helena, Montana 59601**

[For legal notices and all other purposes]

**State of Montana
Office of the Attorney General
Medicaid Fraud Control Unit
303 N. Roberts Street, Room 367
Helena, Montana 59620**

BAYER:

**Assistant General Counsel
Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516**

- 19) BAYER represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 20) The undersigned individuals signing this Agreement on behalf of BAYER represent and warrant that they are authorized by BAYER to execute this Agreement. The undersigned STATE signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

- 21) Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.
- 22) The parties have read the foregoing Agreement and accept and agree to the provisions contained therein and hereby have caused this Agreement to be signed as of the day and date adjacent to their signature.
- 23) The Effective Date of this Agreement shall be the date upon which all the parties below have executed this Agreement.

State of Montana
Office of Attorney General
Medicaid Fraud Control Unit

Bayer Corporation

By: Ruth Seeling Date: 2/21/01 By: Paul R. Brey Date: 8/6/01

Title: Assistant Attorney General Title: Vice President & Asst.
General Counsel

✓ State of Montana Medicaid Program Sidley & Austin, Counsel for BAYER

By: Jenyl C. Davis Date: 2/22/01 By: Pam E. Kalb Date: 8/1/01

Title: Administrator

Paul E. Kalb, Esq.
I. Scott Bass, Esq.
Robert Fabrikant, Esq.

Exhibit "A"
Participating States

ALABAMA
ALASKA
ARKANSAS
CALIFORNIA
COLORADO
CONNECTICUT
DELAWARE
FLORIDA
GEORGIA
HAWAII
IOWA
ILLINOIS
INDIANA
KANSAS
KENTUCKY
LOUISIANA
MASSACHUSETTS
MARYLAND
MAINE
MICHIGAN
MINNESOTA
MISSOURI
MISSISSIPPI
MONTANA
NORTH CAROLINA
NEW HAMPSHIRE
NEW JERSEY
NEW MEXICO
NEVADA
NEW YORK
OHIO
OKLAHOMA
OREGON
PENNSYLVANIA
RHODE ISLAND
SOUTH CAROLINA
SOUTH DAKOTA
TEXAS
UTAH
VIRGINIA
VERMONT
WASHINGTON
WISCONSIN
WEST VIRGINIA
WYOMING

H>

Exhibit "B"
Threshold States

ALABAMA
ARKANSAS
CALIFORNIA
CONNECTICUT
FLORIDA
ILLINOIS
LOUISIANA
MASSACHUSETTS
MARYLAND
MICHIGAN
MINNESOTA
MISSOURI
NORTH CAROLINA
NEW JERSEY
NEW YORK
OHIO
PENNSYLVANIA
SOUTH CAROLINA
TEXAS
VIRGINIA
WASHINGTON
WISCONSIN

Exhibit "C"
Certification Form

CERTIFICATION

The undersigned, a high managerial agent of Bayer Corporation, hereby certifies that the attached average sale price information has been communicated to First DataBank and that it has been calculated in accordance with the methodology described herein. I further acknowledge that the average sale prices so reported will be filed with and used in the administration of the State of Montana Medicaid program.

Signature

Title

Date